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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,221	03/25/2004	Calvin Hanna	06642.105001 CON 2	6553

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,221	HANNA, CALVIN	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/29/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,723,714 or claims 1-12 of US Pat. 6,777,401. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of said US Patents disclose a clear stable one phase solution that is non-irritating and resistant to freezing comprising between about 30% and about 50% water, propylene glycol, 2-propanol or ethanol and hydrocortisone in amount of about 1.2%, and can additionally contain amounts of chloroxylenol, pramoxine or mineral oil, which amounts of said components set forth in said claims of the US Patents fall within the scope of or overlap the claims of the present invention.

The terminal disclaimer filed on 8/29/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patents. 6,723,714 and 6,777,401 has not yet been reviewed and accepted. As such, the rejection has been maintained. Examiner has requested that SPRE review the same.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: trace amounts. The Specification indicates that no more than trace amounts of mineral oil can be added.

Claims 9,10,21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as follows: The claims recited a range of the claimed alcohols from between about 10% (v/v) and about 80%(v/v). However, the amount of water ranges from about 30% to about 50% (v/v). At 80% of the claimed alcohol, the minimum amount of water claimed already exceeds 100% of the volume of the composition. Further, there is no room to add propylene glycol or hydrocortisone. As such, the claims are indefinite.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2,8-10,14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shroot et al. (US Pat. 4,853,379).

Shroot et al. expressly discloses a lotion containing 30 g of propylene glycol, 40 g of ethanol, 10 g of a 50% aqueous solution of dimethyl coco-benzylammonium chloride, 2.5 g of hydrocortisone and sufficient amount of water for a total of 100 g falling within the scope of applicant's claims (Column 3, Example A). The term "about" is not defined in the claims or the specification, as such, the amounts expressly disclosed appear to fall within the scope of the ranges claimed.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978).

Claims 1-10, 13-21, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shroot et al. (US Pat. 4,853,379 in view of Mitra et al. (US Pat. 5,686,089).

Shroot et al. discloses a lotion containing 30 g of propylene glycol, 40 g of ethanol, 10 g of a 50% aqueous solution of dimethyl coco-benzylammonium chloride, 2.5 g of hydrocortisone and sufficient amount of water for a total of 100 g falling within the scope of applicant's claims (Column 3, Example A). A shampoo is disclosed containing 20 g of propylene glycol, 20 g of ethanol, 50 g of a 50% aqueous solution of dimethyl coco-benzylammonium chloride, hydrocortisone and sufficient amount of water for a total of 100 g (Column 3, Example C). It is disclosed that hydrocortisone can be present in an amount of between 0.01 and 5 weight

percent,more particularly between 0.5 and 4 weight percent (Column 2, lines 30-40). It is disclosed that isopropanol is also suitable as an alcohol and that the alcohol can preferably be present in an amount of 15 to 60 weight percent (Column 2, lines 1-3, 18-21). It is disclosed that the amount of propylene glycol can range from 15 to 60 weight percent and that water can range from 10 to 50 weight percent (Column 2, lines 23,25). It is disclosed that the compositions are stable (Column 1, lines 45-63). It is disclosed that the compositions are particularly useful in the treatment of eczema, psoriasis, lupus and erythema (Column 2, lines 58-63).

Mitra et al. disclose the 2,6-dimethyl-4-hydroxychlorobenzene (PCMX) and a range of about 0.1% to about 0.5% (Column 3, lines 1-7, 27) It is disclosed that the compositions are substantially free of water insoluble ingredients, such as hydrocarbon oils, but that the compositions can contain low levels of insoluble ingredients (Column 4, lines 32-40, Column 5, lines 1-19). It is disclosed that mineral oil is a hydrophobic material but that said preparations alone provide only symptomatic relief of dry tissues (Column 1, lines 25-35). It is disclosed that the compositions can include additional co-solvents such as ethanol and isopropanol (Column 4, lines 43-44). It is disclosed that the compositions typically include an organic solvent such as water, propylene glycol, ethanol or isopropanol or mixtures thereof (Column 49-61). It is disclosed that the compositions are preferably visually translucent (Column 4, lines 66,67). It is disclosed that the compositions can include anti-inflammatory and anesthetic agents or mixtures thereof which do not effect the stability of the composition (Column 6, lines 56-64). It is disclosed that the anti-inflammatory agent can be present in a range of about 0.5 to about 5% and include hydrocortisone (Column 7, lines 1-6). It is disclosed that useful or antipruritic drugs

include pramoxine (Column 8, lines 32, 42). It is disclosed that the topical compositions is safe and effective for treating dry membranous tissue and infections (Column 2, lines 35-40).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose adding mineral oil, pramoxine or chloroxylenol. However, the prior art amply suggests the same as the prior art discloses adding minor amounts of mineral oil, and adding pramoxine and chloroxylenol to stable, clear compositions. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that addition of minor amounts of mineral oil would not effect the single phase properties of the composition and that pramoxine would provide desired anesthetic properties and chloroxylenol would provide desired antibacterial properties to the composition.

Further, since the prior art expressly discloses the use of a mixture of alcohol, propylene glycol and water it is inherent that the composition would be resistant to freezing (See Van Nostrand's Scientific Encyclopedia (7th Ed. 1989), pgs. 1229,1230 (freezing point of a solution is in general lower than that of a pure solvent); The Merck Index (11 Ed. 1989), pgs. 820,1247 (isopropyl alcohol and propylene glycol is used in antifreeze compositions); Remington's Pharmaceutical Sciences (17th Ed. 1985), pg. 1463 (solvents such as propylene glycol and alcohol contribute to freezing-point depression). "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). In any case, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a

different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result, i.e. freezing resistance, discovered by applicant. See In re Linter, 173 USPQ 560 (CCPA 1972) ; In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
January 21, 2006

JOHN PAK
PRIMARY EXAMINER
GROUP 1600